Applicant: Michael R. Dupelle et al.

Serial No.: 09/938,063 Filed: August 23, 2001

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REMARKS

Attorney's Docket No.: 04644-101001

After the amendments, there are two independent claims pending (11, 16). (The amendments have been made without prejudice to the original claims being pursued in a continuation application.)

The examiner has rejected the independent claims under 35 USC 103(a) as being unpatentable over Gliner (US 6178357) in view of Smith Ind. (EP 434258A2). The examiner is urged to reconsider and withdraw the rejection.

The invention addresses a problem with external defibrillation electrodes, which are quite large (e.g., 4-5 inches in diameter), relatively thick, and which have a very sticky adhesive to assure good adhesion to the patient. The rescuer must quickly attach the electrodes to the patient in a stressful, emergency situation, and the electrodes must be attached accurately at specific anatomic locations. Application of conventional defibrillation electrodes involves removing a release sheet from an electrode, and then placing the electrode on the patient's chest. As the rescuer begins to place the electrode on the chest, the adhesive will often stick prematurely to the patient's skin or chest hair and limit the rescuer's ability to relocate the electrode to the desired anatomic location. If a portion of the adhesive attaches itself to the patient at an unintended place, significant effort is required to detach the adhesive from the patient before finally placing the electrode at the desired location. This detachment/reattachment process can consume too much time, and result in a dangerous delay of treatment. The invention solves this problem of adhesion to an unintended place by allowing the rescuer to place the electrodes in the desired location, and to fine tune the chosen location, all before removing the release sheet.

In some defibrillation electrodes, the two electrodes are mechanically integrally connected to form one electrode pad assembly, and that assembly must be correctly positioned on the chest of the patient. It is this construction to which the amended independent claims are directed.

Smith Ind., like Kay (US 5713842), which the examiner relied on in the previous action, teaches the use of a release backing for a thin wound dressing. To assure that the thin dressing is applied smoothly without wrinkling, and without contamination, a pair of U-shaped release

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backings are configured to be removed from each side of the wound dressing after the dressing is in position over the wound. It is in this context, that Smith Ind. teaches the use of the U-shaped release backing -- as a means of solving a problem of wrinkling in the application of thin-film wound dressings to the skin.

It would not have been obvious to modify Gliner to substitute the U-shaped release backings of Smith Ind. for the conventional release backing taught in Gliner. No problem is taught in Gliner or in Smith Ind. that would provide any motivation for the combination. The examiner suggests that the motivation would come from the reader of Smith Ind. thinking that the release backing of Smith Ind. could be applied to defibrillation electrodes because the advantage taught in Smith Ind. of avoiding contamination of the electrodes by the fingers would be of advantage in handling defibrillation electrodes. But this is an unreasonable interpretation, for at least two reasons. First, the examiner has no reference that teaches that such finger contamination is a problem needing solution. Second, there is nothing in Smith Ind. suggesting that anything taught in Smith Ind. would be of value to defibrillation electrodes. Smith Ind. does mention at the end of the detailed description that the invention is not confined to dressings that are made of a thin plastics material, but this does not suggest applying the disclosures of Smith Ind. to anything other than wound dressings. It certainly is not a suggestion of applying it to defibrillation electrodes.

Most importantly, there is no suggestion in Gliner of any problem that would be solved by what is taught in Smith Ind. The present inventors appreciated that problems with alignment of the electrodes made the use of a U-shaped release liner advantageous, but Gliner is completely silent on such an alignment problem.

The examiner's combination is, thus, without the required motivation. It is only with the hindsight afforded by the invention that the examiner has found these wound dressing disclosures.

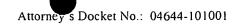
In evaluating obviousness, the examiner needs to keep in mind the long history of conventional release liners in external defibrillation electrodes. Gliner was following a long accepted approach to release liners in defibrillation electrodes. It is simply not reasonable to

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conclude that one skilled in the art would have departed from that long-accepted release liner configuration, particularly when Gliner does not suggest any problem with the disclosed electrodes that could possibly have been solved by substituting the release liners of Smith Ind.

Finally, there is serious question as to whether Smith Ind. is even analogous art, as wound dressings are hardly the area of medical technology that designers of defibrillation electrodes would examine for solutions to problems.

Although, applicants reserve the right to pursue allowance of the unamended claims, the independent claims have been amended to add two limitations: (1) a construction in which two electrodes are mechanically interconnected to form an electrode pad assembly, and in which there is a separate release sheet associated with each of the electrodes; (2) a minimum area requirement on each of the electrodes of the assembly (at least 50 square centimeters).

In light of the weakness of the examiner's rejection -- because it is lacking in motivation for the combination, and in light of the further limitations added to the claim, the examiner is urged to reconsider and withdraw the rejections.

The remaining claims are all properly dependent on one or more of the independent claims, and thus allowable therewith. Each of the dependent claims adds one or more further limitations that enhance patentability, but those limitations are not presently relied upon. For that reason, and not because applicants agree with the examiner, no rebuttal is offered to the examiner's reasons for rejecting the dependent claims.

Allowance of the application is requested.

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Respectfully submitted,

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